

# Legal liability for healthcare-associated infections

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**Summary** As defined by World Health Organization, a nosocomial infection or healthcare-associated infection is an infection occurring in a patient during the process of care in a hospital or other healthcare facility which was not present or incubating at the time of admission. This includes infections acquired in the healthcare facility but appearing after discharge, as well as occupational infections among healthcare workers of the facility.

The Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans defines healthcare-associated infection as “an infection that occurred in connection with the provision of health services, where the disease: did not occur at the time of providing health services during the incubation period or occurred after provision of health services, in a period not longer than the longest incubation period”.

Healthcare providers and facilities owe a legal duty to ensure patient safety. In this article, important recent verdicts regarding nosocomial infections have been subject to legal analysis. They have been discussed in a broad context, including medical malpractice, guilt of doctors and healthcare facilities, the liability of doctors and healthcare facilities for damage caused during treatment and for violation of patient rights, causation and the burden of proof in trials and compensation for damage suffered.

**Key words:** cross infection, malpractice, risk management, legislation, jurisprudence.

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## Background

Medicine should provide the patient with the best available treatment. However, a cure cannot be guaranteed. When referring to healthcare-associated infection (HAI), it must be acknowledged that the healthcare facility is required to do everything to prevent any infection, and if one occurs, to cure the individual without adverse effects, nevertheless, it is not possible to make sure that an infection does not occur at all [1].

In Polish healthcare facilities (e.g. hospitals), infection control activities have been undertaken for years: detection and registration of infections, their analysis and the use of surveillance data for daily, effective infection prevention.

Therefore, the Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans defines healthcare-associated infection as “an infection that occurred in connection with the provision of health services, where the disease: did not occur at the time of providing health services during the incubation period or occurred after the provision of health services, in a period no longer than the longest incubation period” [2].

Current medical legislation emphasises the broad protection of patient rights. Huge achievements have been made in this respect, which can be proved in particular by the judgments of the Supreme Court and the Supreme Administrative Court forming a permanent line of jurisprudence. In this article, important recent verdicts regarding nosocomial infections have been subject to legal analysis.

Recent court verdicts have been broadly discussed, including medical malpractice, guilt of doctors and healthcare facilities (e.g. hospitals), the liability of doctors and healthcare facilities for damage caused during treatment and for violation of patient rights, causation and the burden of proof in trials and compensation for damage suffered.

## Physicians’ independence and responsibility for damage caused

Life and health are the highest individual and social values. Consequently, there is an imperative to use the best treatment methods and the best medical and technical measures.

The Supreme Court judgment of 28 October 1983 analysed the diligence of doctors and other medical personnel in the context of liability for any damage caused [3]. The Supreme Court states that in the field of civil liability for damage caused, the issue of diligence, and in particular the degree of diligence of doctors and other medical personnel, is particularly relevant. The criteria determining the level of requirements in this aspect may be more or less stringent. However, there cannot be any arbitrariness, and all forms of subjective criteria and assessments should be eliminated.

The level of requirements in the sphere of diagnosis and therapy must determine the state of medical knowledge, which should be broadly understood. It covers not only treatment methods but also the use of drugs and medical equipment. The best treatment methods and the best remedies for this should be used.

Administrative orders may not reduce the threshold of requirements and, consequently, the standards of diligence of a healthcare professional.

In a recent case, the court ruled that failure to use single-use syringes must be treated in these circumstances as negligence, justifying the liability of the Polish State Treasury pursuant to Art. 417 of the Civil Code [3].

The judgment of the Court of Appeal in Warsaw of 15 June 2016 specifies liability of a physician for the damage caused by the fault resulting from an individual medical practice.

The court noted that a doctor’s autonomy as regards professional activities does not preclude the recognition that he acts



as a subordinate in the context of Art. 430 of the Civil Code, which is the basis for liability. Hence, a private healthcare institution may, pursuant to Art. 430 of the Civil Code, be liable for damage caused by the fault of the physician in charge of an individual medical practice [4].

## Obligations of medical entities regarding infections

The Supreme Administrative Court has determined that the State Sanitary Inspectorate, as a specialised institution performing public health tasks, by exercising control and supervision over hygiene conditions in various areas of life, has the competence to impose obligations on medical entities [5]. In accordance with Art. 11 paragraph 1 of the Act of 5 December 2008 on preventing and combating infections and infectious diseases in humans, managers of medical entities and other persons providing health services are obliged to take measures to prevent the spread of infections and infectious diseases [2]. The court stated that the provision of Art. 11 paragraph 1 on preventing and combating infections and infectious diseases in humans, as well as other provisions of the third chapter of this Act entitled “Infections related to the provision of health services and other activities in the course of which there is a violation of human tissue continuity”, are constructed in such a way that they indicate who is responsible for specific activities, including:

- a) managers of healthcare entities;
- b) other persons providing health services;
- c) directors of prisons and detention centres;
- d) persons providing health services other than those indicated above.

The Supreme Administrative Court ruled thus that this does not mean, however, that the above-mentioned persons are the only addressees of administrative and legal obligations if the discussed activities result from the activity of the medical nature. In this respect, the provisions of the Act on preventing and combating infections and infectious diseases in humans cannot be analysed without taking into consideration systemic solutions resulting from Art. 4 paragraph 2 of the Act of 15 April 2011 on medical activities [6].

Pursuant to this provision, the rights and obligations of the medicinal entity specified by the statute are exercised by the head of that entity, unless the statute provides otherwise. Therefore, the head of the healthcare entity only performs the duties that are charged to the healthcare provider itself.

It should also be noted that the Act on preventing and combating infections and infectious diseases in humans does not contain its own definition of the head of the medical entity or the medical entity itself. Therefore, these concepts should be understood as they are understood in the legal system, i.e. considering all provisions regulating the area of medical activity. For example, according to Art. 2 paragraph 2 point 1 of the Act on medical activity, the head is also the management board of a capital company. Therefore, the performance of these duties belongs to the head of the entity.

## Responsibility for infection of the patient in the hospital during treatment

The latest court ruling analysing the responsibility for infecting a patient in hospital is the Supreme Court’s judgment of 14 January 2016 [7]. The court reinforced the reasoning that it cannot be assumed that infection of a patient in a hospital during treatment in each case means negligence in terms of sanitary safety. In accordance with Art. 430 of the Civil Code, the premise of the hospital’s liability for damages is always the fault of the doctor and possibly other medical professionals who provide hospital treatment. If the medical staff cannot be attrib-

uted to the faults indicating their guilt, no causal link within the meaning of Art. 361 § 1 of the Polish Civil Code can be observed between medical staff’s activities and the non-pecuniary damage reported by the plaintiff.

In the course of the proceedings, the Regional Court referred to Art. 430 of the Civil Code and submitted that plaintiff had been harmed as a result of his infection with the bacterium *Staphylococcus aureus* during bypass surgery at the respondent medical facility and thus there was a healthcare-associated infection. However, the plaintiff did not prove the fault of the doctors and medical staff in the course of performing therapeutic activities (negligence, medical malpractice, failure to observe hygiene rules and sanitary conditions). Similarly, in the circumstances of the case, there was no evidence that would show at least a high probability that a healthcare-associated infection occurred for reasons incriminating the facility. The Regional Court referred in this regard to evidence from an expert opinion. It has been established that postoperative wound infections are closely related to the accepted method of treatment, i.e. the method of surgical treatment, as well as the biological features of the patient. Infectious microorganisms may originate in a hospital environment due to e.g. poorly sterilised equipment, hands of staff or visitors. The source of infection can also be bacterial flora colonised on the patient’s skin. Hence, bypass treatments are associated with a risk of bacterial infection. The increase in this risk is also influenced by factors directly related to the patient’s condition, e.g. his age, immunosuppression, nutrition, coexistence of other diseases. In addition, the staphylococcus diagnosed in the victim was not a typical strain of hospital origin. Therefore, the plaintiff did not show a causal link between his infection and the medical activities of the defendant institute’s medical staff [7].

## Standard of evidence for causation in healthcare-associated infections

In case law and legal literature, a causal relationship as a premise for liability for a delict should be certain. However, it should be kept in mind that this process of establishing such a relationship is carried out mentally and hypothetically and, in addition concerns, the analysis of a past event. Consequently, when assessing the test result *conditio sine qua non*, one cannot mean 100% certainty in the empirical sense, because this can never be obtained in principle, but certainty in the procedural sense, i.e. demonstrated with an appropriate degree of probability. On this basis, the court concludes that there is a causal link. It should always be remembered that the question about the affiliation *conditio sine qua non* refers to events from the past and essentially tends to determine “what would happen if ...”. Therefore, there is a position that one can risk the claim that a causal link can never be established with 100% certainty, and using the phrase that the causal link is to be established in a “certain” way, we use a portable design, referring to the very high probability of a causal link [8].

The issue of the standard of proof has been particularly noticed in cases of personal injury, in particular in the field of medical processes. The characteristics of these processes are expressed, among others, in that the boundaries determining the parties’ evidential possibilities as to the existence of a causal relationship determine the current state of medical knowledge. Therefore, it cannot be required that the causal connection between a doctor’s conduct (the operation of the medical facility) and the resulting damage be established in an undeniably certain manner or bordering on certainty. As the Supreme Court has ruled, in relation to hospital infections, it is often argued that it is unrealistic to require the plaintiff to strictly prove the moment and path of infection entering the body, because we are dealing with biological processes that are not subject to observation or documentation [9].

In this situation, Polish jurisprudence, with the support of the doctrine, in order to strengthen the protection of the injured patient, eased the evidence requirements for causation by reducing the power of proof in cases involving healthcare-associated infections. In settled case-law, the existence of a “sufficient dose of probability” of causation is considered sufficient [10]. Sometimes the courts use other terms such as “very high”, “high”, “appropriate”, “higher than other sources”, “overwhelming” or “significant” degree of probability. It can be considered that the use of various terms is not associated with a different understanding of the required degree of probability of a causal relationship, but these terms are treated as synonyms. On the other hand, it seems unjustified to define the degree of probability in the discussed cases as “bordering on certainty”, as this will usually be very difficult (and sometimes even unreal) to prove. Determining the proper degree of probability occurs by referring to the principles of logic, indications of knowledge and life experience [8].

It is therefore right to reject the requirement that there be some causal relationship between the patient’s stay in hospital and nosocomial infection. Most often, it is not possible to present such evidence, as in most cases, one can only speak of a high degree of probability, and only occasionally of certainty or exclusivity of the cause [11].

In the judgment of 14 October 1974, the Supreme Court ruled that “if it was established in the case that the sanitary condition of the hospital was extremely bad and that it could lead to infection, and that the infection had actually occurred, the probability of a causal relationship between poor sanitation and infection of the body is so large that it can be assumed that the plaintiff has fulfilled his obligation under Article 6 of the Civil Code. It is not possible to impose on the unrealistic requirement to strictly prove by what means the infection has entered the body. Therefore, if the defendant claims that, despite the established state of affairs, the infection comes from other sources, the burden of proof shifts to the defendant” [12].

In many judgments regarding healthcare-associated infections, the courts accepted the hospital’s negligence by means of a factual presumption (Civil Procedure Code Art. 231), which the defendant may refute by evidence. In the judgment of 14 October 1992, the Court of Appeal in Cracow stated that: “a medical establishment is obliged to exercise due diligence in order to protect patients against the risk of infection with an infectious disease. If the breach of this obligation increases the risk of infection and thus the risk of development of an infectious disease in patient, the medical establishment shall be liable for the damage suffered by the patient, unless it proves that the damage is a consequence of other circumstances. Requiring the injured person to show a direct causal relationship between behaviour increasing the risk of infection and infection with an infectious disease would cause difficulties to the injured person with regard to collecting evidence that cannot be overcome in practice” [13].

## Prima facie reasoning in medical compensation claims

In light of the above judgment of the Supreme Court, the verdict of the Gdansk Court of Appeal was issued on 13 June 2019 [14]. The court also reinforced the reasoning that in so-called medical compensation proceedings, it is not necessary to show a causal relationship between the action (or omission) of the health service and the patient’s damage to a certain extent in the event of nosocomial infection. It is enough to have a relationship with a reasonable degree of probability. The institution of *prima facie* evidence is a way of proof based on factual presumptions (Civil Procedure Code Art. 231), which results in determining a high probability of damage occurring as a result of a specific event. For the application of *prima facie* inference, it is necessary to show the facts underlying the actual presump-

tion, which allows for a conclusion on the likelihood of culpable misconduct by the medical staff of the hospital and its causal relationship to the damage and harm to the injured party.

The verdict of the Court of Appeal in Warsaw of 18 October 2017, which specified the detailed conditions for applying *prima facie* inferences, proved to be significant in this respect [15]. The court reinforced the reasoning that in order to apply *prima facie* inference, it is necessary to prove the facts that form the basis of the presumption of fact, which allows for a conclusion on the probability of culpable misconduct of the medical staff of the hospital and its causal relationship with the harm suffered by the patient. However, it should be stressed that such evidence is not sufficient if it is shown that there is evidence for another cause of infection. If the party against whom the *prima facie* evidence is acting proves that in the specific circumstances of the case the assumed causal relationship did not occur or that the effect was caused by another reason, then the foundation of the settlement cannot be built on the causal relationship established by the court. Although the application of *prima facie* reasoning relieves the party bearing the burden of proof from the tedious demonstration of all stages of the causal relationship between the primary causative event and the damage, it does however require a high probability of the existence of the first and subsequent causative events, allowing them to be treated as undeniable [15].

In case law and literature on the subject, among the reasons justifying the use of the presumption of actual infection of the patient are:

- the fact that the patient was not infected with the disease at the time of admission;
- confirmation of other cases of infection at the same time and in the same hospital;
- negative sanitary and epidemiological assessments;
- failure to comply with the requirements for cleanliness of medical equipment and personnel;
- nosocomial or community type of pathogen that is the source of the disease;
- lack of information about the disease being previously suffered by family members of the patient (and thus that infection could occur as part of family contacts);
- the passage of time from hospitalisation to the finding of signs of infection, corresponding to the medical incubation periods of the disease [16].

In the Polish case-law, the abovementioned circumstances are considered to increase the likelihood of a patient having acquired an infection in a particular hospital and, therefore, they justify the presumption that the infection occurred in the healthcare setting. According to the general adversarial principle, the burden of proof of the facts underlying the presumption of fact lies with the plaintiff. The courts should share the cited views of jurisprudence and literature regarding the admissibility of *prima facie* reasoning in cases involving nosocomial infections. It is worth emphasising that the correctness of this inference is not undermined by the applicant’s allegation that medical staff have not been proven to fail in the pursuit of the sterility of rooms, tools, medicines, dressing materials and other objects in order to prevent pathogens from entering a specific environment, e.g. an open wound. On the basis of *prima facie* reasoning, however, it should be assumed with high probability that infections occurred while the patient has undergone medical procedures. In these types of situations, a common diagnostic error for hospital medical personnel is to discharge the patient home in a situation where the symptoms may suggest some inflammation.

## Criteria for assessing evidence from expert opinion in healthcare-associated infections

According to the general rules on the distribution of the burden of proof, it is the responsibility of the person prove a fact



from which legal consequences arise [17]. Therefore, a patient who is making a claim for nosocomial infections must prove the premises of the defendant's liability, i.e. damage, event causing damage (doctor, medical staff, healthcare facility), adequate causal relationship between the event and damage, as well as the fault of the doctor (healthcare facility). The medical documentation to which the patient or persons authorised by the patient have full access has substantive significance [18]. The Supreme Court, in its judgment of 15 October 1997, stated that "any deficiencies that cannot be remedied in the medical records cannot be used in the trial to the detriment of the patient" [19]. Although the process is adversarial, the court is not devoid of probative initiative. In cases when it comes to supplementing or assessing evidence, the court may admit evidence *ex officio*, e.g. admission of undeclared evidence from medical records or the appointment of additional evidence from an expert opinion [11]. In the "medical process", important evidence is the opinion of experts who – in order to avoid possible suspicion of bias – should be appointed from a different area than the area of professional activity of the doctor who caused the damage [20].

Particularly noteworthy is the analysis of evidence from an expert opinion in court proceedings regarding healthcare-associated infections. On 3 March 2017, the Court of Appeal in Białystok issued a judgment in which it supported the reasoning in which the opinion of an expert is assessed on the basis of criteria for compliance with the principles of logic and common knowledge, the level of expert knowledge, theoretical foundations of the opinion, as well as the method of motivation and consistence of the conclusions expressed in it [21].

In addition, in its judgment of 14 November 2013, the Supreme Court reinforced the current reasoning that an expert should always be summoned to a hearing, regardless of whether the court ordered him to prepare an oral or written opinion. Such a procedure, which implements the legal directness and adversarial principles, allows the parties and the court to ask questions in matters arising from the expert's written opinion, which serves to eliminate doubts that may arise in persons who do not have expertise in the field and to remove ambiguities and contradictions [22].

It is also undisputed in case law and medical law that the hospital is obliged to exercise due diligence in order to protect patients against the danger of infection (Article 355 of the Civil Code). One of the basic rules of due diligence in performing medical procedures, in particular procedures combined with the possibility of damaging patient's blood vessels, is to take all possible actions to ensure optimal sanitary condition. For the expert's opinion on hospital infections, the basic measure of appropriate responsible behaviour is the criterion of due diligence. In the course of treatment, due diligence is mainly such medical procedures that eliminate the potential for infection with other diseases [21]. If the abovementioned criteria are to be used in an expert opinion, shortcomings of analysis and motivation might prevail and the opinion might not be as conclusive, as was the case in the proceedings of the Court of Appeal in Białystok.

It is clear from the case law of the Supreme Court that mere dissatisfaction of a party with an expert judgment does not justify the need for the court to admit evidence from other experts [23]. Nevertheless, the indication of the circumstances justifying the appointment of another expert is at the discretion of the party who should determine the errors, contradictions or other defects of the questioned opinion that disqualify the expert or possibly justify the appointment of additional opinions [24]. The court should explain the circumstances of the case sufficiently, as well as in appeal proceedings, and remove contradictions in evidence by eliminating evidence found to be unreliable. It should always be taken into consideration that the continuation of evidence collection by the plaintiff through expert opinions on nosocomial infections might lead to unjustified postponement of the final judgement.

## Conclusions

In the doctrine of many countries, it is accepted that the healthcare facility is required to ensure the safety of patients, and therefore also protect individuals against viral and bacterial infections, transfusion of infected blood, the use of infected blood products and the use of defective equipment and medical tools.

In recent years, courts have been receiving many damages claims against healthcare facilities, mostly regarding claims of hepatitis B and C infection, sepsis or HIV. The most common causes of nosocomial infections are: failure to comply with health and safety rules by medical staff, insufficient sterilisation and disinfection of medical equipment, inadequate epidemiological supervision and poor therapeutic and sanitary condition of a healthcare facility (e.g. hospital).

In trials, defendant hospitals usually question the fact that patients were infected during hospitalization, demanding that the plaintiff prove with certainty that the source of the infection was the hospital and the fault of the hospital or medical staff.

The competent courts seek to determine the likelihood of infection in the defendant hospital and, if the probability is high, take the action into account. They are often based on factual presumptions pursuant to Art. 231 of the Code of Civil Procedure and on *prima facie* rule of evidence that assumes that the defendant may rebut the evidence.

This problem is becoming more relevant in the current era of the pandemic. Especially in Poland, doctors, nurses, rescuers and patients who became infected with coronavirus during their time in medical facilities constitute a large group of patients. It seems that the coronavirus infection in legal terms is no different from other cases of nosocomial infections. Patients who have been the victim of such an infection are entitled to a certain catalogue of claims. They may request compensation for causing a health disorder, compensation for a violation of a patient's rights or compensation for damage to property. In case of the death of a patient, his relatives are entitled to a claim for compensation.

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